DEC 17 2013

P.O. Box 708
Warsaw, IN 46581-0708
574 267-6131

510(k) Summary

Sponsor:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Romil Sheth Specialist, Regulatory Affairs, Zimmer Inc. Telephone: (574) 371 - 1621 Fax: (574) 371 - 8760
Date Summary Prepared:	10/15/2013
Trade Name:	Zimmer Distal Radius Plating System
Common Name:	Locking Plate System
Classification Name and Reference:	Plate, Fixation, Bone (21 CFR 888.3030); Screw, Fixation, Bone (21 CFR 888.3040)
Product Code:	HRS, HWC
Classification Panel:	Orthopedic/87
Predicate Device(s):	-Stryker® Leibinger Universal Distal Radius System, Stryker, K040022, cleared on March 12th, 2004 - Zimmer® Periarticular Locking Plate System, Zimmer; K040593, cleared on April 12th, 2004

Purpose and Device Description:

The Zimmer Distal Radius Plating System is a plate and screw system intended for internal fixation and stabilization of fractures and osteotomies of the distal radius. The Zimmer Distal Radius Plating System consists of Volar, Medial and Dorsal locking plates. All the plates have screw holes which can accept either locking or non-locking screws and slots which can accept only non-locking screws. Locking screws and pegs may be inserted at 15° in any direction (30° cone) from the nominal screw hole trajectory. Thus, anatomically contoured plate design combined with locking screw technology creates fixed or variable angled constructs for use in simple or multi-fragment fractures. All the plates and screws are made from Ti-6Al-4V ELI alloy. All the plates and screws are Type II anodized except the non-locking screws which are color anodized.

Intended Use:

The Zimmer Distal Radius Plating System is intended for use in surgical reduction, internal fixation, and stabilization of fractures and osteotomies of the distal radius. Examples of distal radius fractures include but are not limited to compression fractures, intra-articular and extra-articular fractures, displaced fractures, fractures in osteopenic bone, non-unions, and mal-unions.

Comparison to Predicate Device:

The Zimmer Distal Radius Plating System is similar in intended use, materials, sterility, and performance characteristics to the predicate devices.

Performance Data (Nonclinical and/or Clinical):

Non-clinical performance and conclusions:

-**Sterilization Validation**: These devices have been validated to demonstrate that at a minimum gamma dose of 20kGy they can be terminally sterilized to a SAL of 10^{-6} or better.

-**Shelf Life**: Accelerated aging test conducted shows that the sterile devices included in this submission have a shelf life of 10 years

-**Biocompatibility**: Biocompatibility testing of the material used to manufacture plates and screws included in this submission was conducted per ISO 10993-1 and Good Laboratory Practices (21 CFR § 58). All testing passed.

-**Performance testing**: Testing performed included; Dynamic/Fatigue construct testing, evaluating the torsional failure strength, driving torque and axial pull out strength for the Zimmer Distal Radius Plating System screws.

The results of non-clinical performance testing demonstrate that the devices are safe and effective and substantially equivalent to the predicate devices.

Clinical performance and conclusions:

Clinical data and conclusions were not needed to show substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 17, 2013

Zimmer, Incorporated
Mr. Romil Sheth
Specialist, Trauma Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581

Re: K133246
Trade/Device Name: Zimmer Distal Radius Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: October 21, 2013
Received: October 22, 2013

Dear Mr. Sheth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133246

Device Name:

Zimmer Distal Radius Plating System

Indications for Use:

The Zimmer Distal Radius Plating System is intended for use in surgical reduction, internal fixation, and stabilization of fractures and osteotomies of the distal radius. Examples of distal radius fractures include but are not limited to compression fractures, intra-articular and extra-articular fractures, displaced fractures, fractures in osteopenic bone, non-unions, and mal-unions.

Prescription Use _X_ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ____ (21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices